



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Timmermans et al.

Serial No.: To be assigned

Filed: November 3, 2003

For: METHOD FOR QUANTIFYING A
RATIO BETWEEN AT LEAST TWO
NUCLEIC ACID SEQUENCES

Examiner: To be assigned

Group Art Unit: To be assigned

Attorney Docket No.: 2183-5581.1US

NOTICE OF EXPRESS MAILING

Express Mail Mailing Label Number: EV325784452US

Date of Deposit with USPS: November 3, 2003

Person making Deposit: Christopher Haughton

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 or PTO/SB/08 be considered by the Examiner and made of record. Copies of U.S. patents are not being submitted pursuant to Pre-OG Notices <<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/idswouscopies.htm>> (visited 9/15/2003). Copies of foreign patent documents and non-patent literature are enclosed pursuant to 37 C.F.R. § 1.98(a)(2).

In accordance with 37 C.F.R. § 1.97(g) and (h), filing of this Information Disclosure Statement is not to be construed as a representation that a search has been made or an admission that the information cited herein is, or is considered to be, material to patentability as defined in

37 C.F.R. § 1.56(b). Further, no representation is made by Applicants herein that no other possible material information as defined in 37 C.F.R. § 1.56(b) exists.

U.S. Patent Documents

<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US - 4,683,194	7-1987	Saiki et al.
US - 5,104,792	04-14-1992	Silver et al.
US - 5,106,727	04-21-1992	Hartley et al.
US - 5,607,834	3-1997	Bagwell
US - 5,948,649	09-07-1999	Stewart et al.
US - 2001021518	09-13-2001	Goudsmit et al.
US - 6,027,880	2-2000	Cronin et al.
US - 6,521,428	02-2003	Senapathy
US- 2003/0022194 A1	01-2003	Erlander et al.
US- 2003/0003488 A1	01-2003	Ramakrishnan
US- 2003-0099933 A1	05-2003	Cote et al.
US- 2002-0169562 A1	11-2002	Stephanopoulos et al.
US- 2002-0049176 A1	04-2002	Anderson et al.
US-2002-0048763 A1	04-2002	Penn et al.
US-5,569,754 A	10-1996	Williams et al.
US-6,221,600 B1	04-2001	MacLeod et al.
US-6,232,065 B1	05-2001	Robinson et al.

Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
WO 96 15264	05-23-1996	JSD Technologies Ltd.
WO 97 30062	08-21-1997	Amsterdam Support

Attorney Docket No.: 2183-5581.1US

		Diagnostics B.V.
WO 98 02575	01-22-1998	Senapathy
WO 01/51661 A2	07-19-2001	Amsterdam Support
		Diagnostics B.V.
EO 0466520	01-15-1992	Life Technologies Inc.
WO 02/20571 A2	03-2002	Goudsmit et al.
WO 96/40902	12-19-1996	Trevigen, Inc.
WO 02/46470 A2	06-13-2002	Primagen B.V.
WO 96/06191 A2	02-29-1996	Akzo Nobel N.V.
		Ramot University Authority
WO 97/39149 A1	10/23/1997	for Applied Research and
		Industrial Development, Ltd.
WO 98/17826 A1	04/30/1998	Mitokor
WO 99/66075 A2	12/23/1999	Mitokor

Other Documents

McGRATH et al., Sequence analysis of DNA randomly amplified from the *Saccharomyces cerevisiae* genome, *Molecular and Cellular Probes*, 1998, pp. 397-405, Vol. 12.

ROSE et al., Consensus-degenerate hybrid oligonucleotide primers for amplification of distantly related sequences, *Nucleic Acids Research*, 1998, pp. 1628-35, Vol. 26, No. 7.

SMITH et al., Automated differential display using a fluorescently labeled universal primer, *Biotechniques*, 1997, pp. 274-79, Vol. 23, No. 2.

GUO et al., Enhanced discrimination of single nucleotide polymorphisms by artificial mismatch hybridization, *Nature Biotechnology*, Vol. 15, pp. 331-335.

LEONE et al., Molecular beacon probes combined with amplification by NASBA enable homogeneous, real-time detection of RNA, *Nucleic Acids Research*, Vol. 26, No. 9, pp. 2150-55, 1998.

MARRAS et al., Multiplex detection of single-nucleotide variations using molecular beacons, *Genetic Analysis: Biomolecular Engineering*, 14, pp. 151-56, 1999.

MORRIS et al., Rapid Reverse Transcription-PCR Detection of Hepatitis C Virus RNA in Serum by Using the TaqMan Fluorogenic Detection System, *Journal of Clinical Microbiology*, Vol. 34, No. 12, pp. 2933-36, December 1996.

TYAGI et al., Multicolor molecular beacons for allele discrimination, *Nature Biotechnology*, Vol. 16, pp. 49-53, January 1998.

ABBOTT, A.G., et al., Quantitative variation of components of the maize mitochondrial genome between tissues and between plants with different male-sterile cytoplasms, *Plant Molecular Biology* 233-40 (1985).

ANDERSON, C.M., et al., Mitochondrial Electron Transport Complexes are Decreased in Skeletal Muscle in Type II Diabetes Mellitus, Abstracts from the 59th Session, Page a259 (June 1999).

BOULTWOOD J., et al., Amplification of mitochondrial DNA in acute myeloid leukaemia, *British Journal of Haematology*, 426-31 (1996).

LEE, H.K., et al., Decreased mitochondrial DNA content in peripheral blood precedes the development of non-insulin-dependent diabetes mellitus, *Diabetes Research and Clinical Practice* 161-67 (1998).

LOCKHART et al., Expression monitoring by hybridization to high

SU, C., et al., Selective reduction of creatine kinase subunit mRNAs in striated muscle of diabetic rats, *American Journal of Physiology* e310-e316 (1992).

TEPPER, C.G., "Resistance of Mitochondrial DNA to Degradation Characterizes the Apoptotic but Not the Necrotic Mode of Human Leukemia Cell Death, *Journal of Cellular Biochemistry* 352-61 (1993).

WILLIAMS R.S., Mitochondrial Gene Expression in Mammalian Striated Muscle. Evidence That Variation in Gene Dosage is the Major Regulatory Event, *J. Biol. Chem.*, 261 (26):12390-94 (1986).

WILLIAMS et al., Regulation of Nuclear and Mitochondrial Gene Expression by Contractile Activity in Skeletal Muscle, *J. Biol. Chem.*, 261(1):376-80 (1986).

VOEHRINGER et al., Gene microarray identification of redox and mitochondrial elements that control resistance or sensitivity to apoptosis. *PNAS* 97(6):2680-5 (MAR 2000).

DeRISI et al., Exploring the metabolic and genetic control of gene expression on a genomic scale, Science, 278(5338):608-6 (OCT 1997).

DeRISI et al., Use of a cDNA microarrays to analyze gene expression patterns in human cancer, Nature Genetics 14(4):457-60 (DEC 1996).

SCHENA M., Genome analysis with gene expression microarrays, Bioessays 18(5): 427-31 (1996).

SCHENA et al., Parallel human genome analysis: microarray-based expression monitoring of 1000 genes, PNAS 93(20):10614-9 (OCT 1996).

SCHENA et al., Quantitative monitoring of gene expression patterns with a complementary DNA microarray, Science 270 (5235):467-70 (1995).

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming a common inventor(s):

Attorney Docket No.: 2183-4760US
Serial No.: 09/785,881
Filing Date: 2/16/2001
Title: REDUCING BACKGROUND IN HYBRIDISATION REACTIONS

Attorney Docket No.: 2183-5189US
Serial No.: 10/006,009
Filing Date: 12/4/2001
Title: TESTING ENDOSYMBIONT CELLULAR ORGANELLES AND COMPOUNDS IDENTIFIABLE THEREWITH

Attorney Docket No.: 2183-5426US
Serial No.: 10/192,786
Filing Date: 7/10/2002
Title: A UNIVERSAL NUCLEIC ACID AMPLIFICATION SYSTEM FOR NUCLEIC ACIDS IN A SAMPLE

Attorney Docket No.: 2183-5581US
Serial No.: 60/425,055
Filing Date: 11/8/2002
Title: METHOD FOR QUANTIFYING A RATIO BETWEEN AT LEAST TWO NUCLEIC ACID SEQUENCES (DUPLEX 2)□

Attorney Docket No.: 2183-5581.1US

This Information Disclosure Statement is filed within three (3) months of the filing date of the above-identified application, and no certification pursuant to 37 C.F.R. § 1.97(c) or a fee pursuant to 37 C.F.R. § 1.17(p) is required.

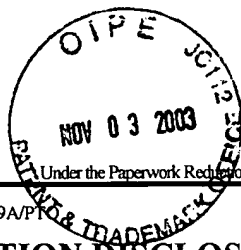
Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Allen C. Turner', with a stylized flourish extending to the right.

Allen C. Turner
Registration No. 33,041
Attorney for Applicant(s)
TRASKBRITT, P.C.
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: November 3, 2003
ACT/bv

Enclosures: Form PTO-1449 or PTO/SB/08
Cited Documents
Document in ProLaw



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Sheet 1 of 3

Complete if Known

Application Number	To be assigned
Filing Date	November 3, 2003
First Named Inventor	Timmermans et al.
Attorney Docket Number	2183-5581.1US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US-4,683,194	7-1987	Saiki et al.	
		US- 5,104,792	04-14-1992	Silver et al.	
		US- 5,106,727	04-21-1992	Hartley et al.	
		US- 5,607,834	3-1997	Bagwell	
		US- 5,948,649	09-07-1999	Stewart et al.	
		US- 2001021518	09-13-2001	Goudsmit et al.	
		US- 6,027,880	2-2000	Cronin et al.	
		US- 6,521,428	02-2003	Senapathy	
		US- 2003/0022194 A1	01-2003	Erlander et al.	
		US- 2003/0003488 A1	01-2003	Ramakrishnan	
		US- 2003-0099933 A1	05-2003	Cote et al.	
		US- 2002-0169562 A1	11-2002	Stephanopoulos et al.	
		US- 2002-0049176 A1	04-2002	Anderson et al.	
		US-2002-0048763 A1	04-2002	Penn et al.	
		US-5,569,754 A	10-1996	Williams et al.	
		US-6,221,600 B1	04-2001	MacLeod et al.	
		US-6,232,065 B1	05-2001	Robinson et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		WO 96 15264	05-23-1996	JSD Technologies Ltd.		
		WO 97 30062	08-21-1997	Amsterdam Support Diagnostics B.V.		
		WO 98 02575	01-22-1998	Senapathy		
		WO 01/51661 A2	07-19-2001	Amsterdam Support Diagnostics B.V.		
		EO 0486520	01-15-1992	Life Technologies Inc.		
		WO 02/20571 A2	03-2002	Goudsmit et al.		
		WO 96/40902	12-19-1996	Trevigen, Inc.		
		WO 02/46470 A2	06-13-2002	Primagen B.V.		
		WO 96/06191 A2	02-29-1996	Akzo Nobel N.V.		
		WO 97/39149 A1	10/23/1997	Ramot University Authority for Applied Research and Industrial Development, Ltd.		
		WO 98/17826 A1	04/30/1998	Mitokor		
		WO 99/66075 A2	12/23/1999	Mitokor		

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 3

Complete if Known

Application Number	To be assigned
Filing Date	November 3, 2003
First Named Inventor	Timmermans et al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	2183-5581.1US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

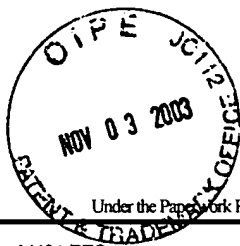
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		McGRATH et al., Sequence analysis of DNA randomly amplified from the <i>Saccharomyces cerevisiae</i> genome, <i>Molecular and Cellular Probes</i> , 1998, pp. 397-405, Vol. 12.	
		ROSE et al., Consensus-degenerate hybrid oligonucleotide primers for amplification of distantly related sequences, <i>Nucleic Acids Research</i> , 1998, pp. 1628-35, Vol. 26, No. 7.	
		SMITH et al., Automated differential display using a fluorescently labeled universal primer, <i>Biotechniques</i> , 1997, pp. 274-79, Vol. 23, No. 2.	
		GUO et al., Enhanced discrimination of single nucleotide polymorphisms by artificial mismatch hybridization, <i>Nature Biotechnology</i> , Vol. 15, pp. 331-335.	
		LEONE et al., Molecular beacon probes combined with amplification by NASBA enable homogeneous, real-time detection of RNA, <i>Nucleic Acids Research</i> , Vol. 26, No. 9, pp. 2150-55, 1998.	
		MARRAS et al., Multiplex detection of single-nucleotide variations using molecular beacons, <i>Genetic Analysis: Biomolecular Engineering</i> , 14, pp. 151-56, 1999.	
		MORRIS et al., Rapid Reverse Transcription-PCR Detection of Hepatitis C Virus RNA in Serum by Using the TaqMan Fluorogenic Detection System, <i>Journal of Clinical Microbiology</i> , Vol. 34, No. 12, pp. 2933-36, December 1996.	
		TYAGI et al., Multicolor molecular beacons for allele discrimination, <i>Nature Biotechnology</i> , Vol. 16, pp. 49-53, January 1998.	
		ABBOTT, A.G., et al., Quantitative variation of components of the maize mitochondrial genome between tissues and between plants with different male-sterile cytoplasms, <i>Plant Molecular Biology</i> 233-40 (1985).	
		ANDERSON, C.M., et al., Mitochondrial Electron Transport Complexes are Decreased in Skeletal Muscle in Type II Diabetes Mellitus, Abstracts from the 59th Session, Page a259 (June 1999).	
		BOULTWOOD J., et al., Amplification of mitochondrial DNA in acute myeloid leukaemia, <i>British Journal of Haematology</i> , 426-31 (1996).	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 3

Complete if Known

Application Number	To be assigned
Filing Date	November 3, 2003
First Named Inventor	Timmermans et al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	2183-5581.1US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		LEE, H.K., et al., Decreased mitochondrial DNA content in peripheral blood precedes the development of non-insulin-dependent diabetes mellitus, 42 Diabetes Research and Clinical Practice 161-67 (1998).	
		LOCKHART et al., Expression monitoring by hybridization to high-density oligonucleotide arrays, Nature Biotechnology 14 (13): 1676-80 (DEC 1996).	
		SU, C., et al., Selective reduction of creatine kinase subunit mRNAs in striated muscle of diabetic rats, 263 American Journal of Physiology e310-e316 (1992).	
		TEPPER, C.G., "Resistance of Mitochondrial DNA to Degradation Characterizes the Apoptotic but Not the Necrotic Mode of Human Leukemia Cell Death, 52 Journal of Cellular Biochemistry 352-61 (1993).	
		WILLIAMS R.S., Mitochondrial Gene Expression in Mammalian Striated Muscle. Evidence That Variation in Gene Dosage is the Major Regulatory Event, J. Biol. Chem., 261 (26):12390-94 (1986).	
		WILLIAMS et al., Regulation of Nuclear and Mitochondrial Gene Expression by Contractile Activity in Skeletal Muscle, J. Biol. Chem., 261(1):376-80 (1986).	
		VOEHRINGER et al., Gene microarray identification of redox and mitochondrial elements that control resistance or sensitivity to apoptosis. PNAS 97(6):2680-5 (MAR 2000).	
		DeRISI et al., Exploring the metabolic and genetic control of gene expression on a genomic scale, Science, 278(5338):608-6 (OCT 1997).	
		DeRISI et al., Use of a cDNA microarrays to analyze gene expression patterns in human cancer, Nature Genetics 14(4):457-60 (DEC 1996).	
		SCHEMA M., Genome analysis with gene expression microarrays, Bioessays 18(5): 427-31 (1996).	
		SCHEMA et al., Parallel human genome analysis: microarray-based expression monitoring of 1000 genes, PNAS 93(20):10614-9 (OCT 1996).	
		SCHEMA et al., Quantitative monitoring of gene expression patterns with a complementary DNA microarray, Science 270 (5235):467-70 (1995).	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.